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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,121	01/18/2002	Randolph M. Howes	2514-0051-01	7866
27874	7590	08/25/2004	EXAMINER	
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ART UNIT		PAPER NUMBER		
1616				

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/050,121	HOWES, RANDOLPH M.
	Examiner Frank I Choi	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 July 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 and 14-46 is/are pending in the application.
 4a) Of the above claim(s) 5,11,17-28 and 30-46 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-4,6-10,12,14-16 and 29 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 18 January 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

In view of the Appeal Brief filed on 4/23/2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Drawings

The drawings are objected to because the following. Figures 12-18 appear to be photocopies of photos. However, the photocopying process rendered the photos unclear such that it is not clear what is being shown in said photos. See 37 CFR 1.84(b).

Photographs . —

- (1) Black and white . Photographs, including photocopies of photographs, are not ordinarily permitted in utility and design patent applications. The Office will accept photographs in utility and design patent applications, however, if photographs are the only practicable medium for illustrating the claimed invention. For example, photographs or photomicrographs of: electrophoresis gels, blots (e.g., immunological, western, Southern, and northern), auto- radiographs, cell cultures (stained and unstained), histological tissue cross sections (stained and unstained), animals, plants, in vivo imaging, thin layer chromatography plates, crystalline structures, and, in a design patent application, ornamental effects, are acceptable. If the subject matter of the application admits of illustration by a drawing, the examiner may require a drawing in place of the photograph. The photographs must be of sufficient quality so that all details in the photographs are reproducible in the printed patent.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

Claims 1-4, 6-10, 12, 14-16, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Ameta et al. in view of the acknowledged prior art, Colic (US Pat. 6,544,401) and Beattie et al. (US Pat. 5,364,344).

Ameta et al. discloses that singlet oxygen can be prepared by photosensitization in which oxygen is passed into a solution containing a dye and a substrate exposed to visible or u.v. light or by the reaction between sodium hypochlorite and hydrogen peroxide in which the other products are NaCl and water (Pgs. 108, 109).

Applicant acknowledges that singlet oxygen is effective against tumor cells and cancer (Paragraph 009). Further, it is acknowledge that the photodynamic method for producing singlet oxygen has several drawbacks, including the problem of untargeted portions of the body being

exposed and expense (Paragraphs 013,014,015). It is disclosed that using a peroxide-hypochlorite anion system singlet oxygen is produced which is identical to that obtained by dye-sensitized photooxidation. (Paragraph 017). It is acknowledged that singlet oxygen is the principle bacterial oxidizing agent employed by human neutrophils and monocyte phagosomes (Paragraph 019). Applicant acknowledges that singlet oxygen is a very short-lived species of oxygen (Paragraph 084).

Colic teaches that the main component of the defense mechanism of phagocytic white cells is hypochlorite ion that is combined with peroxide to enhance the reactivity of the hypochlorite and produce singlet oxygen (Column 3, lines 43-65). Colic discloses a method of preparing a solution for use in health care products similar to that produced by the body by preparing a solution comprising sodium hypochlorite and hydrogen peroxide and purified water (Column 4, lines 11-13, Column 5, lines 18-56). It is taught that numerous modifications of this process are obvious to persons skilled in the art (Column 5, lines 56-60).

Beattie et al. teach the use dual lumen catheters for delivering different fluids into the blood stream (See entire document).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of sodium hypochlorite and hydrogen peroxide to treat tumors. However, the prior art amply suggests the same as it is known in the art to prepare solutions containing sodium hypochlorite and hydrogen peroxide for use in health care products, that sodium hypochlorite and hydrogen peroxide react to form singlet oxygen which is effective against cancer and tumor cells. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the

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expectation that the combination would be effective in treating tumors. Further, one of ordinary skill in the art, knowing that singlet oxygen is a short-lived species, would be motivated to separately combine the peroxide and hypochlorite at the point of use so as to ensure that singlet oxygen is available for treatment of the cancer or tumor cell. Furthermore, one of ordinary skill in the art would expect that by use of a dual lumen catheter the peroxide and hypochlorite could be kept separate until the last possible moment thereby ensuring the maximum concentration of singlet oxygen possible. Also, one of ordinary skill in the art would expect that simultaneous or sequential administration would be effective in treating tumors. See *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959) (obvious to reverse order of prior art process steps); See also *In re Burhans*, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); *In re Gibson*, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

To the extent that Applicant's arguments set forth in the Appeal Brief are applicable, Examiner makes the following response. "There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). The rationale to support a rejection under 35 U.S.C. 103 may rely on logic and sound scientific principle. *In re Soli*, 137 USPQ 797 (CCPA 1963).

Applicant indicates that claim 1 is exemplary of the rejected claims, however, claim 29 does not recite the use of separate sources of peroxide and hypochlorite and does not recite that single oxygen is produced.

Since Schraufstatter et al. is no longer part of the rejection, Applicant's arguments relative to the same appear to be moot. Applicant argues that it was widely recognized and accepted in the medical profession that peroxide and hypochlorite were toxic and should not be administered. Examiner acknowledges Applicant's arguments, however, Applicant's evidence does not disclose a composition in which peroxide and hypochlorite are present or discuss the toxicity of the combination of peroxide and hypochlorite. The prior art teaches that peroxide and hypochlorite will react to form singlet oxygen with the other products being water and sodium chloride and that a solution containing the same can be used in health care products. As such, Applicant's arguments relative to the toxicity of hydrogen peroxide and hypochlorite do not appear to overcome the rejection herein.

Since McCaughan et al. is no longer part of the rejection, Applicant's arguments relative to the same appear to be moot. With respect to photodynamic therapy, Applicant acknowledges that the singlet oxygen produced by photodynamic therapy is the same as that produced the hypochlorite/peroxide reaction, however, that photodynamic therapy is not site specific. Since the singlet oxygen produced by the hypochlorite/peroxide reaction is the same as that produced by photodynamic therapy and singlet oxygen is used to treat cancer, one of ordinary skill in the art would expect that hypochlorite/peroxide solution in which singlet oxygen is produced would also be effective in treating cancer.

Applicant admits that Beattie et al. provides a means for administering two solutions simultaneously, if one wanted to do so. However, Applicant argues that there is no reason why one would want to administer at least one source of peroxide and at least one source of hypochlorite. The prior art as indicated above does suggest the combination of hypochlorite and peroxide for treatment of mammals, as such, the teachings of Beattie et al. are relevant. Further, the prior art discloses that singlet oxygen is an extremely short-lived species. As such, one of ordinary skill in the art would expect that the more immediate in time the peroxide and hypochlorite are mixed to produce singlet oxygen and in distance from the point of administration to the time of and desired area of treatment the more singlet oxygen will be available to act on the tumor cell or cancer. The dual lumen catheter would permit one to have the site of treatment be the site of administration and the time of mixing be the time of administration and treatment, thereby maximizing the amount of singlet oxygen for treatment of the tumor cell or cancer.

Contrary to Applicant's arguments there is a reasonable expectation of success in that the prior art discloses that hydrogen peroxide and sodium hypochlorite will react to form water, sodium chloride and singlet oxygen, that singlet oxygen is effective in treating cancer and tumor cells and that a solution containing hydrogen peroxide and sodium hypochlorite can be used in health care products. Contrary to Applicant's arguments the prior art does suggest all the claim limitations as the prior art disclose that sodium hypochlorite and hydrogen peroxide are mixed to form singlet oxygen.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

August 19, 2004



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